UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,697	09/27/2001	Tarlochan Singh Dhadialla	2584.0270002/RWE/GER	4412

80011 7590 02/15/2011

Sterne, Kessler, Goldstein & Fox P.L.L.C.
1100 New York Avene
N.W.
Washington, DC 20005

EXAMINER	
SHAFER, SHULAMITH H	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
02/15/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/965,697	DHADIALLA ET AL.	
	Examiner	Art Unit	
	SHULAMITH H. SHAFER	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7,9,10,12 and 50-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7,9,10,12 and 50-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/24/10 and 1/10/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Status of Application, Amendments, And/Or Claims:

Applicants' amendment of 19 November 2010 is acknowledged. Claims 1, 4, 9 and 12 have been amended and the amendment made of record. Claims 55-70 are newly presented and entered into the record.

Claims 1-4, 7, 9, 10, 12, and 50-70 are pending and under consideration in the instant application.

Information Disclosure Statement:

The Information Disclosure statements (IDS) submitted on the 24 November 2010 and 10 January 2010 have been considered. The signed copies are attached.

Objections

Claim 56 objected to because of the following informalities: there is a trypographical error in the claim. In lines 4-5 of the claim "an ecdysone receptor ligand binding domain " is recited without identifying the species comprising said ligand binding domain. Appropriate correction is required.

Rejections

Double Patenting Rejections:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 7, 50-52 and 55-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4 and 21-36 of copending application SSN 12/707,599

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claim 1 of the co-pending application is drawn to a multiple inducible gene modulation system comprising a plurality of individually operable gene modulation systems, wherein each individually operable gene modulation system comprises:
a) a first gene expression cassette comprising:
A) a DNA binding domain that recognizes a response element associated with a gene of interest:
B) an ecdysone receptor_ligand binding domain; and
b) a second gene expression cassette comprising a promoter operably linked to a

potynucleotide sequence that encodes a second polypeptide comprising a nuclear receptor ligand binding domain and a transactivation domain;
wherein each individually operable gene modulation system is orthogonal to the other individually operable gene modulation system present in the multiple inducible gene modulation system.

This claim substantially overlaps the limitations of claims 1 and 2 of the instant invention. The remainder of the claims of each application is drawn to viruses comprising the gene regulatory systems, host cells, specific ligand binding domains, specific DNA binding domains, and specific transactivation domains.

Thus, claims 1, 3, 4 and 21-36 of copending application SSN 12/707,599 substantially overlap claims 1-4, 7, 50-52 and 55-66 of the instant invention.

This is a provisional double patenting rejection since the conflicting claims have not, in fact, been patented.

35 U.S.C. § 112, Second Paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 1-4, 7, 9, 10, 12 and 50-54 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained and applied to newly submitted claims 55-70 for reasons of record and for reasons set forth below.
Claim 1 is indefinite in reciting, at section a):

"i) a polynucleotide encoding a receptor complex comprising:
A) a DNA binding domain;
B) an ecdysone receptor ligand binding domain and a nuclear receptor ligand binding domain capable of forming a dimer with the ecdysone receptor ligand binding domain;
C) a transactivation domain;"

It is unclear if Applicants intend a ***single polynucleotide*** to encode a single chimeric polypeptide comprising a DNA binding domain, an ecdysone receptor ligand

binding domain, a second nuclear receptor ligand binding domain and a transactivation domain or ***a first polynucleotide*** encoding a polypeptide comprising a DNA binding domain and an ecdysone receptor ligand binding domain and ***a second polynucleotide*** encoding a second polypeptide comprising a nuclear receptor ligand binding domain capable of forming a dimer with the ecdysone receptor ligand binding domain and a transactivation domain or ***a first polynucleotide*** encoding a polypeptide comprising a DNA binding domain, an ecdysone receptor ligand binding domain and a second nuclear receptor ligand binding domain and ***a second polynucleotide*** encoding a polypeptide encoding a transactivation domain or something else entirely.

Claim 2 is indefinite in reciting, at section b):

"b) i) a first gene expression cassette comprising a polynucleotide that encodes a polypeptide comprising a transactivation domain, a DNA-binding domain that recognizes a response element associated with a gene whose expression is to be modulated; and an ecdysone_receptor ligand binding domain,

ii) a nuclear receptor ligand binding domain selected from the group consisting of a vertebrate retinoid X receptor ligand binding domain, an invertebrate retinoid X receptor ligand binding domain, an ultraspiracle protein ligand binding domain, and a chimeric ligand binding domain comprising two polypeptide fragments, wherein the first polypeptide fragment is from a vertebrate retinoid X receptor ligand binding domain, an invertebrate retinoid X receptor ligand binding domain, or an ultraspiracle protein ligand binding domain, and the second polypeptide fragment is from a different vertebrate retinoid X receptor ligand binding domain, invertebrate retinoid X receptor ligand binding domain, or ultraspiracle protein ligand binding domain"

It is unclear if Applicants intend ***a single polynucleotide*** to encode a single chimeric polypeptide comprising a transactivation domain, a DNA-binding domain, an ecdysone_receptor ligand binding domain and a second nuclear receptor ligand binding domain or ***a first polynucleotide*** encoding a polypeptide comprising a transactivation domain, a DNA-binding domain and an ecdysone_receptor ligand binding domain and ***a second polynucleotide*** encoding a polypeptide comprising a second nuclear receptor ligand binding domain.

Claim 9 is vague and indefinite in reciting, at section a):

“i) a receptor complex comprising:
A) a DNA binding domain;
B) an ecdysone receptor ligand binding domain and a nuclear receptor ligand binding domain capable of forming a dimer with the ecdysone receptor ligand binding domain; and
C) a transactivation domain;”

It is unclear if the receptor complex comprises ***a single polypeptide*** comprising a DNA binding domain, an ecdysone receptor ligand binding domain, a nuclear receptor ligand binding and a transactivation domain or ***a first polypeptide*** comprising a DNA binding domain and an ecdysone receptor ligand binding domain and ***a second polypeptide*** comprising a second nuclear receptor ligand binding domain and a transactivation domain or some other combination of polypeptides.

The Examiner requires clarification as the disclosure teaches only the following working examples:
“A polynucleotide encoding the C, D, E, and F domains from fruit fly Drosophila melanogaster EcR ("DmEcR-CDEF"; SEQ ID NO: 1) was fused to a polynucleotide encoding a GAL4 DNA binding domain ("Gal4DNABD" or "Gal4DBD"; SEQ ID NO: 2) and placed under the control of a cytomegalovirus (CMV) promoter/enhancer (SEQ ID NO: 3). A polynucleotide encoding the C, D, E, and F domains from spruce budworm Choristoneura fumiferana EcR ("CfEcR-CDEF"; SEQ ID NO: 4) was fused to a polynucleotide encoding a LexA DNA binding domain ("LexADNABD" or "LexADBD"; SEQ ID NO: 5) and placed under the control of a cytomegalovirus (CMV) promoter/enhancer (SEQ ID NO: 3). A polynucleotide encoding a chimeric EF domains polypeptide from mouse Mus musculus retinoid X receptor isoform .alpha. ("MmRXR.alpha.") and locust Locusta migratoria ultraspiracle protein ("LmUSP-EF") (SEQ ID NO: 6) was fused to a polynucleotide encoding a transactivation domain from VP16 ("VP16AD"; SEQ ID NO: 7) and placed under the control of a CMV promoter/enhancer (SEQ ID NO: 3) [paragraph 0282]. A polynucleotide encoding the C, D and E domains from green leafhopper Nephotetix cincticeps ecdysone receptor

("NcEcR-CDE"; SEQ ID NO: 15) was fused to a polynucleotide encoding a GAL4DNA binding domain ("GAL4DBD"; SEQ ID NO: 2) and placed under the control of a cytomegalovirus (CMV) promoter/enhancer (SEQ ID NO: 3). A polynucleotide encoding the E and F domains from mouse Mus musculus retinoid X receptor isoform .alpha. ("MmRXR.alpha."; SEQ ID NO: 16) was fused to a polynucleotide encoding a transactivation domain from VP16 ("VP16AD"; SEQ ID NO: 7) and placed under the control of a CMV promoter/enhancer (SEQ ID NO: 3) [paragraph 0283].

Thus, the only working examples are directed to polynucleotides encoding polypeptides comprising a DNA binding domain, and an ecdysone ligand binding domain and polynucleotides encoding polypeptides comprising a transactivation domain and a chimeric RXR-USP ligand binding domain. There are no examples, working or prophetic, of polynucleotides encoding, for example, chimeric polypeptides comprising an ecdysone ligand binding domain and a second ligand binding domain.

Applicants traverse the rejection (Remarks of 19 November 2010, page 13, bridging page 15). The reasons for the traversal are:

In the multiple inducible gene regulation system of independent claims 1 and 9, for each of the orthogonal gene regulation systems, the DNA binding domain, the ecdysone receptor ligand binding domain, the nuclear receptor capable of forming a dimer with the ecdysone receptor ligand binding domain, and the transactivation domain operate together as components of a receptor complex which regulates the transcription of a gene of interest in response to a ligand that binds to the ecdysone receptor ligand binding domain.

In claim 1, for each of the orthogonal gene regulation systems, the receptor complex can be encoded by a single polynucleotide. Alternatively, components of the receptor complex can be encoded by one or more polynucleotides. Pending independent claim 1 recites "a polynucleotide encoding a receptor complex comprising ....

Regardless of whether the receptor complex in each of the orthogonal gene regulation systems in the multiple inducible gene regulation system of claim 1 is encoded by one polynucleotide or more than one polynucleotide, claim 1 is definite.

For at least the same reasons, the claims that depend from claim 1 are definite.

In pending independent claim 9, for each of the orthogonal gene regulation systems, the receptor complex can be a single polypeptide. Alternatively, components of the receptor complex can be encoded by one or more polypeptides.

Regardless of whether the receptor complex in each of the orthogonal gene regulation systems in the multiple inducible gene regulation system of claim 9 is one polypeptide or is more than one polypeptide, the invention of claim 9 is definite.
For at least the same reasons, the claims that depend from claim 9 are definite.

Applicant's arguments have been fully considered but are not found to be persuasive for the following reasons:

The fact that there are two, plausible alternative interpretations of the independent claims of the instant invention render the claims indefinite. It is suggested that Applicants amend the claims to clearly recite the claimed alternatives.

Claim 2 recites the limitation "operable gene regulation system of claim 1". There is insufficient antecedent basis for this limitation in the claim, as claim 1 is drawn to an "orthogonal gene regulation systems".

Claim 57 is vague and indefinite in reciting "the multiple inducible gene modulation system of claim 22". Claim 22 is a canceled claim. Thus, the metes and bounds of claim 57 cannot be determined.

The remainder of the claims is included in the rejection as dependent upon a rejected claim.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7, 9, 10, 12, and 50-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim (s)

contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Written Description Training Materials, Revision 1, March 25, 2008.

The Examiner is interpreting

Claim 1, one of the independent claims to read on a ***single polynucleotide*** encoding a receptor complex comprising:

A) a DNA binding domain;

B) an ecdysone receptor ligand binding domain;

C) a nuclear receptor ligand binding domain capable of forming a dimer with the ecdysone receptor ligand binding domain; and

D) a transactivation domain;

Claim 2(b) to read on a

i) a first gene expression cassette comprising a ***single polynucleotide*** that encodes a polypeptide comprising a transactivation domain, a DNA-binding domain that recognizes a response element associated with a gene whose expression is to be modulated; and an ecdysone receptor ligand binding domain and

ii) a nuclear receptor ligand binding domain selected from the group consisting of a vertebrate retinoid X receptor ligand binding domain, an invertebrate retinoid X receptor ligand binding domain, an ultraspiracle protein ligand binding domain, and a chimeric ligand binding domain comprising two polypeptide fragments, wherein the first polypeptide fragment is from a vertebrate retinoid X receptor ligand binding domain, an invertebrate retinoid X receptor ligand binding domain, or an ultraspiracle protein ligand binding domain, and the second polypeptide fragment is from a different vertebrate retinoid X receptor ligand binding domain, invertebrate retinoid X receptor ligand binding domain, or ultraspiracle protein ligand binding domain,

Claim 9, the other independent claim of the instant invention to read on a gene regulation system comprising a receptor complex comprising ***a single polypeptide*** comprising

A) a DNA binding domain;

B) an ecdysone receptor ligand binding domain;

C) a nuclear receptor ligand binding domain capable of forming a dimer with the ecdysone receptor ligand binding domain; and

D) a transactivation domain

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of claims 1 and 2 indicate that these claims are drawn to a genus, i.e., a ***single polynucleotide*** encoding a receptor complex comprising:

A) a DNA binding domain;

B) an ecdysone receptor ligand binding domain;

C) a nuclear receptor ligand binding domain capable of forming a dimer with the ecdysone receptor ligand binding domain; and

D) a transactivation domain;

A review of the language of claim 9 indicates that this claim is drawn to a genus i.e., a ***a single polypeptide*** comprising

A) a DNA binding domain;

B) an ecdysone receptor ligand binding domain;

C) a nuclear receptor ligand binding domain capable of forming a dimer with the ecdysone receptor ligand binding domain; and

D) a transactivation domain

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a

substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states, "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

There are no species of the above claimed genera disclosed in the specification. Applicants disclose only the following working examples:
"A polynucleotide encoding the C, D, E, and F domains from fruit fly Drosophila melanogaster EcR ("DmEcR-CDEF"; SEQ ID NO: 1) was fused to a polynucleotide encoding a GAL4 DNA binding domain ("Gal4DNABD" or "Gal4DBD"; SEQ ID NO: 2) and placed under the control of a cytomegalovirus (CMV) promoter/enhancer (SEQ ID NO: 3)" [paragraph 0282].

Thus, a polynucleotide encoding the LBD from Drosophila melanogaster EcR and the GAL DNA binding domain is disclosed.
"A polynucleotide encoding the C, D, E, and F domains from spruce budworm Choristoneura fumiferana EcR ("CfEcR-CDEF"; SEQ ID NO: 4) was fused to a polynucleotide encoding a LexA DNA binding domain ("LexADNABD" or "LexADBD"; SEQ ID NO: 5) and placed under the control of a cytomegalovirus (CMV) promoter/enhancer (SEQ ID NO: 3)" [paragraph 0282].

Thus, a polynucleotide encoding the LBD from Choristoneura fumiferana EcR and the LexA DNA binding domain is disclosed

"A polynucleotide encoding a chimeric EF domains polypeptide from mouse Mus musculus retinoid X receptor isoform alpha. ("MmRXRalpha.") and Locusta migratoria ultraspiracle protein ("LmUSP-EF") (SEQ ID NO: 6) was fused to a polynucleotide

encoding a transactivation domain from VP16 ("VP16AD"; SEQ ID NO: 7) and placed under the control of a CMV promoter/enhancer (SEQ ID NO: 3)" [paragraph 0282].

Thus, a polynucleotide encoding a chimeric LBD from mouse RXR-alpha and and Locusta migratoria ultraspiracle protein and the VP16 transactivation domain is disclosed.

"A polynucleotide encoding the C, D and E domains from green leafhopper Nephotetix cincticeps ecdysone receptor ("NcEcR-CDE"; SEQ ID NO: 15) was fused to a polynucleotide encoding a GAL4DNA binding domain ("GAL4DBD"; SEQ ID NO: 2) and placed under the control of a cytomegalovirus (CMV) promoter/enhancer (SEQ ID NO: 3)" [paragraph 0283].

Thus, a polynucleotide encoding a LBD from Nephotetix cincticeps ecdysone receptor and a GAL4DNA binding domain is disclosed.

"A polynucleotide encoding the E and F domains from mouse Mus musculus retinoid X receptor isoform alpha. ("MmRXR.alpha."; SEQ ID NO: 16) was fused to a polynucleotide encoding a transactivation domain from VP16 ("VP16AD"; SEQ ID NO: 7) and placed under the control of a CMV promoter/enhancer (SEQ ID NO: 3) [paragraph 0283].

Thus, a polynucleotide encoding a LBD from mouse RXR-alpha and a VP16 transactivation domain is disclosed.

The only working examples are directed to polynucleotides encoding polypeptides comprising a DNA binding domain, and an ecdyson ligand binding domain and polynucleotides encoding transactivation domain and a mouse RXR or a chimeric RXR-USP ligand binding domain. There are no examples, working or prophetic, of polynucleotides encoding, for example, chimeric polypeptides comprising an ecdysone ligand binding domain and a second ligand binding domain.

Thus, claims of the instant invention encompass numerous species that are not further described.

In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genera, which are a ***single polynucleotide*** encoding a receptor complex comprising: A) a DNA

binding domain; B) an ecdysone receptor ligand binding domain; C) a nuclear receptor ligand binding domain capable of forming a dimer with the ecdysone receptor ligand binding domain; and D) a transactivation domain and ***a single polypeptide*** comprising: A) a DNA binding domain; B) an ecdysone receptor ligand binding domain; C) a nuclear receptor ligand binding domain capable of forming a dimer with the ecdysone receptor ligand binding domain; and D) a transactivation domain.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus. The specification does not clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Conclusion:

No claims are allowed.

In light of the new grounds of rejection, this Office Action is non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHULAMITH H. SHAFER whose telephone number is (571)272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shulamith H. Shafer/
Primary Examiner, Art Unit 1647